

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

14. Jan. 2005

PCT

To:

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WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year) 13.01.2005

Applicant's or agent's file reference
81-9270

REPLY DUE **within 1 month(s)**
from the above date of mailing

International application No.
PCT/CH 03/00523

International filing date (day/month/year)
30.07.2003

Priority date (day/month/year)
31.07.2002

International Patent Classification (IPC) or both national classification and IPC
A61K9/08

Applicant
PHAFAG AG et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 30.11.2004

Name and mailing address of the international preliminary examining authority:



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I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-11 as originally filed

Claims, Numbers

1-38 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

WRITTEN OPINIONInternational application No. **PCT/CH 03/00523**

Novelty (N)	Claims	1-5,11,15-18,24,27-30,34,36,38
Inventive step (IS)	Claims	1-38
Industrial applicability (IA)	Claims	

2. Citations and explanations**see separate sheet**

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: EP0542689 (PHAFAG) 19 May 1993 (1993-05-19)

D2: EP0032564 (MEDICHEMIE) 29 July 1981 (1981-07-29)

D3: WPI/DERWENT AN 1983-45789K (& JP58057317, MITSUBISHI CHEM. IND. LTD., JP) ; 5 April 1983 (1983-04-05)

D4: WO9966931 (PHAFAG) 29 December 1999 (1999-12-29)

D5: WO9204011 (ALZA) 19 March 1992 (1992-03-19)

D6: WO9200729 (ALZA) 23 January 1992 (1992-01-23)

V.1. The present application does not meet the criteria of **Article 33(1) PCT**, because the subject-matter of **present claims 1-3,11,15-17,24,28-30,34,36,38** is not new in the sense of **Article 33(2) PCT** in the light of the **document D1**.

In fact the document D1 discloses (the references in parentheses applying to this document) **pharmaceutical compositions comprised of the same compounds as in the present Application and a carrier for the treatment of inner ear conditions (such as tinnitus or impaired hearing). The compositions can be liquid compositions and the carrier can be an aqueous carrier (see D1, claims; page 4, lines 38-41 and 47-58).**

Analogously, the present application does not meet the criteria of **Article 33(1) PCT**, because the subject-matter of **present claims 1-2,4-5,11,15-16,18,24,27-28** is not new in the sense of **Article 33(2) PCT** in the light of the **document D2**.

In fact the document D2 discloses (the references in parentheses applying to this document) **pharmaceutical oral or parenteral compositions comprised of the same compounds as in the present Application and a carrier for the treatment of a variety of conditions. The compositions can be liquid compositions and the carrier can be an aqueous carrier and/or a carrier containing e.g. fatty acids (salts or alcohols) or a glycol (see D2, claims 13,14,19,32; page 2, last paragraph-page 4, last paragraph).**

As far as the **document D3** is concerned, the same considerations as for the **document D2** are applicable (*see D3, abstract*).

On the other hand, the present application does not meet the criteria of **Article 33(1) PCT**, because the subject-matter of **present claims 1-3,11,15-17,24,28-29,36,38** is not new in

the sense of **Article 33(2) PCT** in the light of the **document D4**.

In fact the document D4 discloses (the references in parentheses applying to this document) **pharmaceutical topical or transdermal, oral or parenteral compositions comprised of the same compounds as in the present Application and a carrier for the treatment of conditions due to impaired hearing nerve. The compositions can be liquid compositions and the carrier can be an aqueous carrier or e.g. a glycerol-based topical dermal carrier** (*see D4 , claims 8,9,11; examples 1-3, 10-11*).

Finally, both the **documents D5 and D6** are prejudicial to the novelty of **present claims 1-2,15-16,28**.

In fact both the documents D5 and D6 disclose (the references in parentheses applying to these documents) **pharmaceutical oral layered osmotic compositions comprised of the same compound Caroverine as in the present Application and a carrier** (*see D5, claims ; example 5; see D6, claims ; example 2*).

In conclusion, the present application does not meet the criteria of **Article 33(1) PCT**, because the subject-matter of **present claims 1-5,11,15-18,24,27-30,34,36,38** is not new in the sense of **Article 33(2) PCT** in the light of all the **above mentioned documents D1 to D6**.

V.2. Furthermore, the subject-matter of **present claims 1-38** does not seem to involve an inventive step in the sense of **Article 33 (3) PCT**, and therefore the requirements of **Article 33 (1) PCT** are not met.

In fact the **documents D1 to D6** mentioned above in **paragraph V.3.** all appear to be of particular relevance as far as the inventive step is concerned (**Article 33 (3) PCT**).

These documents solve indeed the same **problem** as defined in the present Application (*see in particular the description, page 2, line 28 - page 3, line 17*), namely **the preparation of caroverine (salts, analogs) liquid aqueous or non-aqueous compositions comprised of the active agent and a carrier, to be administered topically or systemically for the treatment of ear conditions.**

Therefore - **as far as novel subject matter is concerned** - the present Application does not seem to fulfill the requirements of **Article 33 (3) PCT** over this prior art documents.

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/CH 03/00523

VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT
AUF DEM GEBIET DES PATENTWESENS

Absender: ANMELDEAMT

An:

CHARGE

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PCT

MITTEILUNG DES INTERNATIONALEN
AKTENZEICHENS UND DES
INTERNATIONALEN ANMELDEDATUMS

(Regel 20.5 c) PCT)

Absendedatum (Tag/Monat/Jahr)

31. Juli 2003 (31.07.03)

Aktenzeichen des Anmelders oder Anwalts

81-9270

WICHTIGE MITTEILUNG

Internationales Aktenzeichen

PCT/CH 03/00523

Internationales Anmelddatum (Tag/Monat/Jahr)

30. Juli 2003 (30.07.03)

Prioritätsdatum (Tag/Monat/Jahr)

31. Juli 2002 (31.07.02)

Anmelder

Phafag AG, 9486 Schaanwald et al.

Bezeichnung der Erfindung

A Pharmaceutical Formulation and its Use in the Treatment of Inner Ear Diseases.

1. Dem Anmelder wird mitgeteilt, dass der internationalen Anmeldung das oben genannte internationale Aktenzeichen und internationale Anmelddatum zuerkannt worden ist

2. Weiterhin wird dem Anmelder mitgeteilt, dass das Aktenexemplar der internationalen Anmeldung

☒ dem Internationalen Büro am 08.08.03 übermittelt wird.

☐ dem Internationalen Büro noch nicht übermittelt wurde,

☐ weil die erforderliche Überprüfung zum Schutz der nationalen Sicherheit noch nicht erfolgt ist.

☐ weil (Angabe des Grundes):

☒ Ein Exemplar dieser Mitteilung ist dem Internationalen Büro übersandt worden (da das Aktenexemplar dem Internationalen Büro noch nicht übermittelt wurde). *

* Das Internationale Büro überwacht die Übermittlung des Aktenexemplars durch das Anmeldeamt und unterrichtet den Anmelder über dessen Eingang (mit Formblatt PCT/IB/301). Ist das Aktenexemplar bei Ablauf des vierzehnten Monats nach dem Prioritätsdatum noch nicht eingegangen, teilt das Internationale Büro dies dem Anmelder mit (Regel 22.1 c)).

Name und Postanschrift des Anmeldeamts

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